

EXHIBIT A

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION MDL No. 2804  
OPIATE LITIGATION

Case No.  
1:17-md-2804

Judge Dan Aaron  
Polster

This Document Relates To:

The County of Lake, Ohio v.  
Purdue Pharma L.P., et al.  
Case No. 18-op-45032

The County of Trumbull, Ohio v.  
Purdue Pharma L.P., et al.,  
Case No. 18-op-45079

Track 3 Cases

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Remote videotaped deposition of
JOSEPH RANNAZZISI

September 22, 2021
2:29 p.m.

Renee L. Pellegrino, RPR, CLR
(Appearing Remotely)

1 Q. If you think of any others while
2 we're together today, will you please let me
3 know?

4 A. Sure.

5 Q. Do you have any personal knowledge
6 based on public information of any other chain
7 pharmacy in Ohio filling illegitimate
8 prescriptions?

9 MR. BENNETT: Objection. Vague as
10 to time.

11 Q. At any time.

12 A. Personal knowledge based on
13 publicly available information, no.

14 Q. You don't have any -- strike that.
15 Do you have any personal knowledge
16 based on publicly available information of a
17 Walgreens pharmacist in Ohio filling a
18 prescription that was later diverted?

19 A. Personal knowledge, no.

20 Q. What about anywhere else in the
21 country? Do you have any personal knowledge
22 based on public information of a Walgreens
23 pharmacist filling a prescription that was
24 later diverted?

25 A. I have knowledge of situations

1 A. I only -- my information base is
2 based on my time at the Office of Diversion
3 Control, and much of it is non-public.

4 Q. Do you have any other information
5 other than that you've shared already, any
6 other public information, personal knowledge
7 about public information related to any
8 Walgreens pharmacist anywhere filling a
9 prescription that was later diverted?

10 A. No.

11 Q. Have you ever been -- strike that.
12 What about any other chain
13 pharmacy, Walmart, CVS, Giant Eagle, Rite-Aid?
14 Do you have any personal knowledge of any of
15 their pharmacists in Ohio ever filling a
16 prescription that was later diverted?

17 MR. BENNETT: Objection.

18 Same instruction regarding
19 non-public information from DEA investigations
20 or activities. To the extent you can answer
21 that question with publicly available
22 information, you may.

23 A. I don't have any publicly
24 available information pertaining to that.

25 Q. Have you ever been inside a

1 Walgreens pharmacy in a professional capacity
2 during your tenure at the DEA?

3 A. No.

4 MR. BENNETT: Objection.

5 I'll withdraw the objection since
6 he answered no.

7 Q. What about CVS, Walmart, Giant
8 Eagle, any other chain pharmacy? Have you
9 ever been in any of those pharmacies in a
10 professional capacity while you were at the
11 DEA?

12 MR. BENNETT: Objection.

13 Instruct the witness that he's not
14 authorized to answer based on non-public DEA
15 investigations or activities. To the extent
16 that you can answer with publicly available
17 information or non-investigative information,
18 you may answer.

19 A. I have not been in any of those
20 pharmacies in a professional capacity.

21 Q. You identified one investigation
22 that you were -- that you were aware of that
23 was publicly available relating to Walgreens.
24 In the course of that investigation did you
25 ever meet with anybody who worked at

1 other pharmacies.

2 Q. Do you have that understanding
3 based on anything other than conversations
4 with pharmacists at conferences?

5 A. No. I've never worked the system
6 so I wouldn't have any hands-on training on
7 the system.

8 Q. Do you have any hands-on
9 experience with any other chain pharmacy's
10 computer system?

11 A. No.

12 Q. Have you ever reviewed
13 prescription dispensing data from any
14 Walgreens pharmacy in Lake or Trumbull County,
15 Ohio?

16 MR. BENNETT: Objection.

17 You're not authorized to disclose
18 any specific non-public DEA investigations or
19 activities during your time at DEA. To the
20 extent that you can answer the question with
21 publicly available information or non-DEA
22 information, you may answer.

23 MR. UTTER: I'll add to that, Mr.
24 Rannazzisi, to the extent you've done any work
25 for any plaintiffs' counsel in any other case,

1 mine.

2 MS. SWIFT: That one, I apologize.
3 It must have been added late. It's in the
4 ExhibitShare, along with all of the other
5 exhibits, and I'm happy to put it up on the
6 screen, if that's helpful for folks.

7 UNIDENTIFIED VOICE: I don't have
8 it either, for what it's worth.

9 - - - - -

10 (Thereupon, Deposition Exhibit 23,
11 Declaration of Joseph Rannazzisi,
12 Beginning Bates Stamp
13 P-08343_00002, was marked for
14 purposes of identification.)

15 - - - - -

16 MS. SWIFT: It is in the
17 ExhibitShare for all to see. It's Exhibit 23.
18 And please tell me if folks can see that on
19 their screen.

20 UNIDENTIFIED VOICE: It's pretty
21 small, but my cracker jack team has given me a
22 copy, so I'm good to go, Kate. Thank you.

23 Q. Can you see that, Mr. Rannazzisi?

24 A. I can see that.

25 Q. Is that the declaration that you

1 signed in the Holiday CVS case?

2 A. Can you put it to the last page so
3 I could look at it?

4 Q. Sure thing.

5 A. That's my signature, yes.

6 Q. All right. I'm going to take you
7 to paragraph 26. Do you see, Mr. Rannazzisi,
8 that paragraph 26 refers to a meeting between
9 DEA and CVS personnel in Florida on December
10 8th, 2010?

11 A. Yes.

12 Q. And the information about that
13 meeting carries over to the next page and on
14 through to paragraph 32. My question for you
15 about it is did you attend that meeting?

16 A. No, I did not attend that meeting.

17 Q. All right. Starting at paragraph
18 33, there's a reference to another meeting
19 between DEA and CVS on August 12th, 2011.

20 Do you see that?

21 A. Yes.

22 Q. Did you attend that meeting?

23 A. No, I did not.

24 Q. If you'll take a look at paragraph
25 41. The declaration that you wrote states

1 that DEA interviewed CVS employees at two CVS
2 pharmacies in Sanford, Florida, correct?

3 A. Yes.

4 Q. You did not attend those
5 interviews, did you?

6 A. No, I did not.

7 Q. Did your declaration reflect your
8 recollection of the DEA's investigation of
9 these two CVS pharmacies in Florida?

10 A. My -- that declaration is my
11 knowledge of those investigations at that
12 point in time during the investigation, yes.

13 Q. Is there anything missing from
14 your declaration that you can think of sitting
15 here today?

16 MR. BENNETT: Objection.

17 The witness is not authorized to
18 disclose non-public DEA investigation
19 information. To the extent there was
20 additional information gathered during that
21 investigation that was not made public, the
22 witness is not authorized to disclose that
23 information.

24 A. And that is the extent of the
25 public information that was available.

1 Q. Did you personally meet with
2 anyone at CVS as a part of DEA's investigation
3 to the extent that that's publicly available?

4 A. I did not personally meet with
5 anyone from CVS.

6 Q. Other than the two CVS pharmacies
7 and the Holiday CVS case, did you participate
8 in any public DEA investigations of CVS
9 pharmacies?

10 A. I don't -- I don't recall any
11 participation with -- hands-on participation
12 in any of those investigations with CVS, no.

13 Q. Did you participate in any public
14 DEA investigations of Walgreens?

15 A. When you say "public
16 investigations," what -- what are you
17 referring to?

18 Q. I mean DEA investigations that are
19 publicly available. I believe you testified
20 earlier the only one you're aware of involving
21 Walgreens was the Florida investigation. Did
22 you participate in that investigation?

23 A. Well, if I'm not mistaken -- I
24 haven't looked at those documents in a long
25 time, but I seem to remember that I signed the

EXHIBIT B

IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE:
NATIONAL PRESCRIPTION
OPIATE LITIGATION

CASE TRACK THREE

Case No. 1:17-md-2804
Cleveland, Ohio

October 5, 2021
8:59 A.M.

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VOLUME 2

- - - - -

TRANSCRIPT OF JURY TRIAL PROCEEDINGS,
BEFORE THE HONORABLE DAN A. POLSTER,
UNITED STATES DISTRICT JUDGE,
AND A JURY.

- - - - -

Official Court Reporter: Susan Trischan, RMR, CRR, FCRR, CRC
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801 West Superior Avenue
Cleveland, Ohio 44113
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Proceedings recorded by mechanical stenography;
transcript produced by computer-aided transcription.

1 you have -- if you see it as a problem.

2 Okay?

3 First of all, I referenced to the jury in
4 opening Plaintiffs' 8954, which is a settlement agreement
14:10:27 5 that was entered into between CVS and the Drug
6 Enforcement Administration.

7 Are you familiar with this settlement
8 agreement?

9 MR. DELINSKY: Your Honor, the same 408 and
14:10:43 10 403 objections.

11 THE COURT: Overruled.

12 What's the date of this one?

13 MR. LANIER: 2015, Your Honor. It's
14 Florida.

14:10:48 15 THE COURT: Overruled.

16 BY MR. LANIER:

17 Q. Are you familiar with this, sir?

18 A. I don't believe I've ever seen this form before,
19 this particular document.

14:10:58 20 Q. Sir, this is in the wheelhouse of what you do,
21 though?

22 You even have people negotiating these
23 agreements, don't you?

24 A. Our attorneys and our legal department handle
14:11:15 25 settlements, sir.

1 Q. Well, Nickie Harrington, you have complimented
2 before for negotiating down a settlement value.

3 Haven't you?

4 MR. DELINSKY: Objection, Your Honor.

14:11:25 5 THE COURT: Overruled.

6 A. Not that I can recall.

7 BY MR. LANIER:

8 Q. Okay. If -- all right. In this settlement
9 agreement, are you familiar with your company
14:11:41 10 acknowledging that it has a corresponding responsibility
11 to dispense only those prescriptions that have been
12 issued for a legitimate medical purpose by an individual
13 practitioner acting in the usual course of professional
14 practice and that knowingly filling a prescription not in
14:12:00 15 the usual course of professional treatment or in
16 legitimate and authorized research subjects CVS to
17 penalties?

18 Are you familiar with that?

19 A. I'm just reading it, I mean it makes sense, right.
14:12:23 20 It says we're complying with the law.

21 Q. Did your company also acknowledge that certain CVS
22 Pharmacy retail stores did dispense controlled substances
23 in a manner not fully consistent with their compliance
24 obligations under the CSA and its implementing
14:12:40 25 regulations?

1 Did you know about that?

2 A. Yes, sir.

3 Q. So you knew that your company had been dispensing
4 controlled substances in a manner not fully consistent,
14:12:53 5 and in your mind that's not a problem.

6 Is that what I'm to understand?

7 MR. DELINSKY: Objection, Your Honor.

8 THE COURT: It --

9 MR. DELINSKY: It states the agreement
14:13:05 10 incorrectly.

11 THE COURT: It was a compound question.

12 MR. LANIER: All right. I'll rephrase.

13 THE COURT: Break it down, please, just one
14 at a time.

14:13:13 15 BY MR. LANIER:

16 Q. Sir, do you consider it a problem to dispense
17 certain controlled substances in a manner not fully
18 consistent with compliance obligations under the
19 Controlled Substances Act and its implementing
14:13:36 20 regulations?

21 A. Yes, that would be a problem.

22 Q. So is it fair to say that the CVS, at least in 2015
23 in Florida, admitted to a problem?

24 A. In the case of two individual stores, yes. They
14:13:55 25 admitted to a problem.

1 When I answered your question earlier, sir,
2 I was thinking about the full context of our entire
3 operation in the 10,000-plus stores that we operate
4 across the country.

14:14:09 5 And I do not believe that there are any
6 systemic problems.

7 Q. All right.

8 A. That was my testimony.

9 Q. I will show you Plaintiffs' Exhibit 8955.

14:14:24 10 And this is another settlement agreement
11 dealing with Maryland in 2016.

12 Are you familiar with the agreement
13 settling the Maryland dispute in 2015?

14 MR. DELINSKY: Your Honor, same 408, 403
14:14:43 15 objection.

16 THE COURT: Overruled.

17 Mr. Lanier, you gave two dates.

18 First you said 2015 and then you said 2016.

19 MR. LANIER: Apologize, Your Honor.

14:14:52 20 This is 2016.

21 THE COURT: All right.

22 MR. DELINSKY: And, Your Honor, that's the
23 date of the agreement; not the allegations.

24 The allegations are many years before.

14:15:02 25 THE COURT: The agreement is dated February

1 of 2016 so --

2 BY MR. LANIER:

3 Q. And that's my question, sir.

4 Are you familiar with the agreement entered
14:15:13 5 into in February of 2016 concerning Maryland?

6 A. I'm aware that there -- sir, that there is a
7 settlement agreement.

8 I have never read the agreement that's put
9 before me so I don't profess to know all the details in
14:15:31 10 it.

11 Q. And I won't ask you all of the details, but I'll
12 ask you are you familiar with this detail.

13 CVS Pharmacy retail stores, plural, in
14 Maryland, did dispense certain controlled substances in a
14:15:43 15 manner not fully consistent with their compliance
16 obligations under the CSA and its implementing
17 regulations by not conducting corresponding
18 responsibility when dispensing certain controlled
19 substances in some instances between 2008 and 2012?

14:16:04 20 Are you familiar with that agreement?

21 A. I am familiar with the issue that's identified,
22 yes, sir.

23 Q. And when you look at this, and I ask you has CVS
24 had problems, would you agree with me that you need to
14:16:29 25 add the Maryland stores?

1 A. If we're looking at individual stores, yes, you
2 would add the Maryland stores.

3 Q. Yeah, we're looking at CVS Pharmacy retail stores
4 in Maryland between 2008 and 2012.

14:16:47 5 Would you agree with me there were problems
6 there?

7 A. As indicated in the settlement agreement, there
8 were issues.

9 Q. So is that a yes, you would agree with me that
14:17:02 10 there were problems there?

11 A. Yes.

12 Q. And those are the two that I spoke with the jury
13 about in opening, but they're not the only two, are they?

14 A. They're not the only two what, sir?

14:17:23 15 Q. Agreements that you have had with the Government
16 over CVS's behavior.

17 True?

18 A. The -- there are other settlement agreements that
19 the company has entered into.

14:17:37 20 Q. So Plaintiffs' 10214, Your Honor, this is 2014 out
21 of Texas.

22 You know about the Texas settlement issues,
23 don't you?

24 A. I am familiar, yes.

14:18:03 25 Q. And this is one where the company doesn't

1 necessarily agree with the findings, but agreed to settle
2 it anyway.

3 Right?

14:18:19 4 A. I am not conversant, sir, with the terms of this
5 stipulated agreement that you've handed to me.

6 Q. All right. Without knowing all of the terms of it,
7 if you will look at Paragraph 7, the United States
8 contends it has certain civil claims against --

9 THE COURT: You've asked him to look at it.

14:18:37 10 MR. LANIER: Oh.

11 THE COURT: So --

12 BY MR. LANIER:

13 Q. Do you have Paragraph 7 in front of you?

14 A. I'm reading it right now.

14:18:46 15 (Pause.)

16 A. I've read it, sir.

17 Q. Are you familiar with the claims made against your
18 company -- by the way, these agreements, these issues are
19 exactly what you're over within CVS, aren't they?

14:19:18 20 A. These are all, in this particular settlement
21 agreement, this is dealing with license verification.

22 We have a different department that handles
23 that technology. That doesn't fall within my group.

24 Q. No, but your group is responsible for making sure
14:19:45 25 that only valid prescriptions are filled, right?

1 A. Well, my group is responsible for supporting the
2 professional practice of pharmacy, and that would be part
3 of that, yes.

4 Q. Right. So the idea that eight separate CVS
14:19:58 5 Pharmacies filled 153 prescriptions for controlled
6 substances from a doctor whose registration was expired,
7 that's something that you should know about, isn't it?

8 MR. DELINSKY: Your Honor, objection.

9 THE COURT: Overruled.

14:20:14 10 MR. BUSH: These are --

11 A. Mr. Lanier, what I can tell you is that when the
12 Government raises an issue like this, we take it very
13 seriously.

14 THE COURT: Hold on.

14:20:25 15 Sir, you were simply asked is this
16 something you would have been apprised of or known of?

17 THE WITNESS: And that's what I'm about to
18 say, yes.

19 A. It's brought to my attention and the attention of
14:20:39 20 my team well before any settlement it brought into place,
21 so, yes, we are made aware of that.

22 And then we take swift action to remediate
23 any issues or make any enhancements that we need to.

24 BY MR. LANIER:

14:20:52 25 Q. Would you agree with me, then, that if eight stores

1 were, indeed, filling prescriptions, 153, during a time
2 where the doctor's registration was expired, that would
3 be a problem, wouldn't it?

4 A. That would be a problem, sir.

14:21:08 5 And in that time period, of the alleged
6 conduct, I actually wasn't in my role, but by the time I
7 did come into my role I know that the company had already
8 begun to make enhancements to the system that we use to
9 ensure that we can do a real-time license check on
10 prescribers.

11 Q. Okay.

12 A. Which would have remediated this issue.

13 Q. And tell me if I've been fair to your testimony
14 where I've written this note because you may not be aware
14:21:40 15 of it, but your company did not agree with all of these
16 findings and so I put, "If the doctor's registration was
17 expired," then the Texas 2012 would be a problem.

18 Fair?

19 A. If we had agreed, yes. I mean if --

14:22:02 20 Q. In other words, if the Government was right in what
21 y'all ultimately settled, then that would have been a
22 problem.

23 Fair?

24 A. Well, I, as I understand it, we didn't admit or
14:22:14 25 deny the allegation, but nonetheless, we have always

1 taken the view that if we have an opportunity to learn
2 from feedback that we get from our customers or
3 regulators or our own employees, we take that to heart
4 and we look to improve our system, sir.

14:22:36 5 Q. Okay. And you're also familiar with the settlement
6 agreement that your company entered into in Rhode Island
7 in 2015.

8 True?

9 MR. LANIER: Your Honor, or Ms. Fleming,
14:22:53 10 it's Plaintiffs' 10212 and, Rachel, 10212. Thank you.

11 BY MR. LANIER:

12 Q. Do you have that agreement in front of you, sir?

13 A. Yes, I do.

14 Q. And I assume you are familiar with this agreement
14:23:17 15 which was entered into in 2015 in your home state of
16 Rhode Island?

17 A. Can I have a moment to review the document?

18 Q. Yes, sir. If it helps you time-wise, the
19 allegations are indented on Page 3.

14:23:36 20 (Pause.)

21 MR. DELINSKY: Your Honor, same 408, 403
22 objections.

23 THE COURT: It's noted.

24 Thank you, Mr. Delinsky.

14:24:10 25 BY MR. LANIER:

1 Q. Do you have that in front of you, sir?

2 A. I'm reading it, yes.

3 Q. Have you had a chance to look and to see those
4 three contentions by the U.S.?

14:24:19 5 A. I'm reading the third one, sir.

6 Q. I apologize for interrupting you.

7 A. Yes, sir.

8 Q. Sir, my question to you is this: Are you familiar
9 with this settlement agreement that was entered into by

14:24:49 10 your company, whether you've read the actual document or
11 not?

12 A. Yes, sir.

13 Q. And so if we look at the three allegations that are
14 given on Page 3, the DEA investigation was one that

14:25:06 15 centered on filling prescriptions with invalid prescriber
16 DEA numbers.

17 Let's just pause there.

18 Is that a bad thing to do?

19 A. Well, that certainly would be against the
14:25:24 20 regulation.

21 Q. Excellent. It's unlawful, fair to say, by your
22 understanding of the law.

23 Right?

24 A. Correct.

14:25:33 25 Q. Or under circumstances where the pharmacist filling

1 the prescription knew or had reason to know that the
2 prescription in question was invalid or unauthorized,
3 that would also be unlawful.

4 True?

14:25:51 5 A. It's my understanding, yes.

6 Q. Okay. And this is -- these are allegations that
7 were settled by your company in Rhode Island in 2015.

8 True?

9 A. Yeah, the -- the document seems to be signed in
14:26:27 10 August of 2015.

11 Q. All right. And if we wanted to keep going, we
12 could talk about Massachusetts, couldn't we?

13 You're familiar with the settlement
14 agreement out of Massachusetts, true?

14:26:43 15 A. There is a settlement agreement in Massachusetts,
16 yes.

17 MR. LANIER: And it is Plaintiffs' 10213,
18 please, Ms. Fleming, Ms. Lanier.

19 BY MR. LANIER:

14:27:19 20 Q. Do you have Plaintiffs' Exhibit 10213, a settlement
21 agreement dealing with Massachusetts in front of you?

22 A. Yes, I do, sir.

23 MR. DELINSKY: Your Honor, same 408, 402
24 and 403 objections.

14:27:32 25 THE COURT: That's noted.

1 Thank you.

2 Q. Sir, you are familiar with these terms, aren't you,
3 or allegations?

4 A. Yes, sir.

14:27:47 5 Q. And we can see them on Paragraph E of the front
6 page.

7 "The United States contends that it has
8 certain civil claims against CVS arising from CVS having
9 filled the 523 forged opioid prescriptions listed in
14:28:10 10 Attachment A hereto."

11 Do you see that, sir?

12 A. Yes, sir.

13 Q. Now, that's unlawful if, indeed, that happened.

14 True?

14:28:20 15 A. Well, the act of attempting to get a controlled
16 substance by subterfuge or deceit is certainly unlawful
17 on the part of the person passing the forged
18 prescription.

19 Our pharmacists do their very best to
14:28:41 20 identify criminal activity.

21 Q. With due respect, sir, you don't know that to be
22 true, do you?

23 You don't have personal knowledge of all
24 10,000 stores, their pharmacists and what efforts they
14:28:53 25 give or don't give.

1 Right?

2 A. Well, with all due respect, Mr. Lanier, I don't
3 know it to not be true, also.

4 Q. But you're swearing to something based upon your
14:29:05 5 personal knowledge, and when you take an oath and swear
6 that everyone tries their best, I'm just probing you on
7 that.

8 You don't know that to be true, do you?

9 A. I believe that to be true.

14:29:15 10 Q. Okay. Please answer my question.

11 You don't know that to be true, do you?

12 THE COURT: He did. All right?

13 So let's move on, please.

14 BY MR. LANIER:

14:29:30 15 Q. Do you think that the pharmacists in Florida were
16 doing their very best when they were unlawfully
17 distributing and dispensing prescriptions?

18 MR. DELINSKY: Objection, Your Honor.

19 THE COURT: Overruled.

14:29:45 20 A. Mr. Lanier, I don't have any firsthand knowledge of
21 the pharmacists' activities.

22 Obviously, you know, there's a settlement
23 in place acknowledging that, you know, there were
24 problems in that store, and I -- I think, I just feel
14:30:09 25 terrible over that.

EXHIBIT C

EXHIBIT D

EXHIBIT

23

PLAINTIFFS TRIAL
EXHIBIT

P-08343_00001

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HOLIDAY CVS, L.L.C.,
d/b/a CVS/Pharmacy Nos. 5195/219

Plaintiff,

v.

ERIC HOLDER, JR., *et al.*,

Defendant.

Civ. No. 1:12-cv-191

DECLARATION OF JOSEPH RANNAZZISI

I, Joseph Rannazzisi, pursuant to 28 U.S.C. § 1746, declare and state as follows:

1. I am currently the Deputy Assistant Administrator for DEA's Office of Diversion Control. In that capacity I coordinate the day-to-day operations of the Diversion Control Program; brief representatives from the pharmaceutical industry, members of Congress, executive staff at the Department of Justice and the Office of National Drug Control Policy, as well as the general public on the national epidemic of prescription drug abuse and the diversion of controlled substance pharmaceuticals.
2. I am a Special Agent of the United States Department of Justice, Drug Enforcement Administration (DEA) and have been employed by the DEA since 1986. Additionally, I have a Bachelor of Science Degree in Pharmacy and am a licensed pharmacist. I also hold a Juris Doctorate from the Detroit College of Law at Michigan State University.

3. Matters contained in this declaration are based upon my personal knowledge, training, experience, and upon conclusions and determinations reached by me. I participated in the decision-making process that led to the issuance of an Immediate Suspension Orders (ISOs) against Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #219 (CVS 219) and CVS/Pharmacy #5195 (CVS 5195) (collectively, "CVS") on February 2, 2012. The contents of the declaration, including history, facts, conclusions, and determinations, were before DEA prior to the issuance of the ISOs against CVS 219 and CVS 5195.

Regulatory Scheme

4. The Food and Drug Administration generally regulates pharmaceutical drugs. Congress, however, recognized the need for greater scrutiny over controlled substances, due to their potential for abuse and danger to public health and safety. As such, it established a separate framework under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, and implementing regulations, that creates a closed system of distribution for all controlled substances and listed chemicals. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
5. Congress therefore established a comprehensive regulatory scheme in which controlled substances are placed in one of five "Schedules" depending on their potential for abuse, the extent to which they may lead to psychological or physical dependence, and whether they have a currently accepted medical use in treatment in the United States. *See* 21 U.S.C. § 812(b). Controlled substances in "Schedule I" have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and a "lack of accepted safety for use under medical supervision."

21 U.S.C. § 812(b)(1)(A)-(C). Controlled substances in Schedule II do have “a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, but still have “a high potential for abuse.” “Abuse of the drug or other substances may lead to severe psychological or physical dependence.” 21 U.S.C. § 812(b)(2)(A)-(C).

6. The CSA gives the Drug Enforcement Administration broad authority to prevent the diversion of pharmaceutical drugs for illicit use. *See* 21 U.S.C. §§ 824(d), 871(a); 21 C.F.R. §§ 1316.65(c) and 1316.67; 28 C.F.R. § 0.104, Appendix to Subpart R, Sec. 7(a). “Diversion” is a term used to describe instances when licit drugs leave the closed-system of distribution for illicit purposes.
7. As part of that authority, the DEA Office of Diversion Control regulates every link in the prescription-drug supply chain and is responsible for regulating more than 1.4 million DEA registrants. Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration with DEA. 21 C.F.R. § 1301.11. It is the responsibility of the Office of Diversion Control to ensure that these registrants adhere to all aspects of the CSA and implementing regulations and to take action against them when they are out of compliance.
8. The closed system of the CSA is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system.

9. Specifically, with respect to pharmacies, registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 C.F.R. § 1306.04(a). Pharmacists are required to ensure that prescriptions for controlled substances are “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a).
10. When registrants at every level—practitioners, pharmacies and distributors—fail to fulfill their obligations, these necessary checks and balances collapse. Because pharmacies are the entity providing the controlled substances to the end user, they are often the last major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. It is, therefore, incumbent on pharmacies to ensure that controlled substances are only dispensed pursuant to valid prescriptions issued for legitimate medical purposes in the usual course of professional practice.
11. When a pharmacy is not adhering to its legal obligations, the DEA has authority to revoke or suspend its registration. *See* 21 U.S.C. § 823(f) (describing that issuance of a practitioner’s registration (including pharmacies) must be consistent with the public interest, as determined by the following five factors: (1) the recommendation of the appropriate State licensing board or professional disciplinary authority; (2) the applicant’s experience in dispensing, or conducting research with respect to

controlled substances; (3) the applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances; (4) compliance with applicable State, Federal, or local laws relating to controlled substances; and (5) such other conduct which may threaten the public health and safety). Ordinarily, DEA must hold a hearing prior to revocation or suspension of an entity's registration. But when the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," DEA has discretion to suspend that party's registration immediately, prior to an administrative hearing. 21 U.S.C. § 824(d). DEA must provide the basis for its suspension in an Order to Show Cause. 21 C.F.R. § 1301.36(e). A Section 824(d) suspension remains in effect until the DEA issues a final order, unless the suspension is withdrawn by the Attorney General or dissolved by a court of competent jurisdiction. 21 U.S.C. § 824(d). A Section 824(d) suspension only suspends a registrant's ability to handle controlled substances and does not affect the registrant's ability to handle non-controlled pharmaceutical drugs.

The Rampant Problem of Controlled Substance Diversion for Illicit Use

12. Prescription drug abuse occurs in the United States at an alarming rate. The 2010 National Survey on Drug Use and Health reveals that approximately 7 million Americans abuse controlled substance pharmaceuticals for non-medical purposes. See 2010 National Survey on Drug Use and Health Survey, (2010 Survey) available at <http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.pdf>. Second only to marijuana, controlled substance prescription drugs are abused by more people than cocaine, heroin, hallucinogens and inhalants combined.

13. Of all prescription drugs, narcotic pain relievers such as oxycodone, hydrocodone, and oxymorphone are abused most frequently. Each year, roughly 5.1 million people abuse narcotic pain relievers in the United States. Oxycodone is a Schedule II controlled substance. *See* 21 C.F.R. § 1308.12(b)(1)(xiii).
14. Over the past several years, DEA has seen two major schemes used to divert powerful and addictive controlled substance pharmaceuticals. First, between 2005 and 2009, hydrocodone, a Schedule III controlled substance, was illegally diverted through rogue Internet pharmacy schemes. Florida was the epicenter for many of the illegal operations whereby tens of millions of dosage units of hydrocodone were diverted to locations across the United States. For reference, a dosage unit is most commonly applied to a tablet. It is the main ingredient, expressed in milligrams or milliliters (liquids), in combination with other ingredients, binders and fillers. Congress reacted to the plethora of rogue Internet pharmacies with the passage of the Ryan Haight Online Pharmacy Consumer Protection Act that took effect in April 2009. This action along with intensified law enforcement actions virtually eliminated domestic-based rogue Internet pharmacies.
15. Second, beginning in late 2008 and continuing to the present, there has been a significant rise in the number of rogue pain clinics whose complicit doctors initially dispensed millions of dosage units of oxycodone, a Schedule II controlled substance more potent than the hydrocodone that was previously dispensed through the rogue Internet operations. Again, Florida was and remains the epicenter for these illegal pain clinics. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based pain clinics to obtain their

supply of oxycodone, and other controlled substances such as alprazolam, which is in turn illegally redistributed in states along the entire east coast and Midwest.

16. Florida has attempted to address this problem through a patchwork of legislation.

Some of the more current state legislation has placed a restriction on a physician's ability to dispense oxycodone from the clinic. The illicit pain clinics responded by issuing prescriptions for oxycodone rather than dispensing directly to the drug seeker.

17. According to the Florida Medical Examiner's Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just five drugs: methadone, oxycodone, hydrocodone, benzodiazepines, or morphine. This is an average of 11.2 persons dying in the state of Florida every day from just these five drugs alone.

18. Furthermore, the abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as the "trinity" or "holy trinity," hydrocodone or oxycodone used in combination with alprazolam (a benzodiazepine) and carisoprodol. According to the Florida Medical Examiner's Office, they have seen a 127% increase in the number of deaths associated with benzodiazepines in the State of Florida between 2005 and 2010.

19. Florida has tried to rein in prescription-drug abuse by enacting laws that limit Florida physicians' ability to dispense controlled substances. Until 2010, FLA. STAT. § 465.0276 allowed a practitioner to dispense drugs in the usual course of professional

practice so long as s/he was registered as such and paid a \$100 fee. The practitioner was subject to the same record-keeping requirements and periodic inspections as a pharmacy. In 2010, the Florida legislature amended FLA. STAT. § 465.0276 to prohibit a registered practitioner from dispensing more than a 72-hour supply of any controlled substance for any patient who paid for the medication with cash, check or credit card. The law became effective October 1, 2010. Finally, in 2011, the Florida legislature amended the statute a second time to prohibit a practitioner, except in very limited circumstances, from dispensing any controlled substances in Schedules II and III. The law became effective July 1, 2011.

20. On July 1, 2011, the State Health Officer and Surgeon General, Dr. Frank Farmer issued a statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida, titled "State Surgeon General Declares Public Health Emergency Regarding Prescription Drug Abuse Epidemic." The press release noted that "In 2010, 98 of the top 100 doctors dispensing Oxycodone nationally were in Florida;" that "In 2010, 126 million Oxycodone pills were dispensed through the top 100 dispensing pharmacies in Florida;" "More Oxycodone is dispensed in the state of Florida than in the remaining states combined." Attachment 1.
21. The changes in the law have changed the way drug abusers obtain oxycodone. Rather than dispensing the drug directly to "patients," pain clinics and complicit doctors now write prescriptions for oxycodone. Drug abusers wanting their prescriptions filled must take their script to retail pharmacies like CVS 219 and CVS 5195.

22. Following these changes in the law, law enforcement saw immediate and significant increases in the volume of oxycodone dispensed from retail pharmacies across the state of Florida.
23. The doctors and clinics that prescribe oxycodone inappropriately, the pharmacies that dispense their prescriptions, including CVS 219 and CVS 5195, have caused, and continue to cause, millions of dosage units of oxycodone to be diverted for unlawful use thereby creating an imminent threat to the public health and safety.

CVS 219 and CVS 5195

24. CVS 219, located at 3798 Orlando Drive, Sanford, Florida 32773 is registered with the DEA as a chain pharmacy in Schedules II, III, IV and V controlled substances under DEA Registration Number BC5289055. DEA Registration Number BC5289055 expires by its terms on December 31, 2013. Attachment 2.
25. CVS 5195, located at 4639 W. 1st Street, Sanford, Florida 32771 is registered with the DEA as a chain pharmacy in Schedules II, III, IV and V controlled substances under DEA Registration Number BC6988298. DEA Registration Number BC6988298 expires by its terms on December 31, 2013. Attachment 3.

Notice to CVS of Diversion Problem

26. On December 8, 2010, DEA hosted a meeting with CVS at the DEA West Palm Beach Resident Office. In attendance at the meeting were representatives from DEA, the Florida Department of Health (DOH) and CVS (including counsel for CVS/Caremark, Inc. and the district supervisor for CVS 219 and CVS 5195).
- Specifically, the following individuals were present:

- a. Group Supervisor Susan Langston, DEA
- b. Group Supervisor Gayle Lane, DEA

- c. Diversion Investigator Phyllis Garret, DEA
- d. Supervisor Michelle Miller, DOH
- e. Senior Pharmacist Robert DiFiore, DOH
- f. John Gilbert, Counsel for CVS/Caremark
- g. District Supervisor, Jennifer Lalani, RPh, CVS
- h. District Supervisor, Papatya Tankut, RPh, CVS

27. The meeting commenced with a brief statement by John Gilbert, counsel for

CVS/Caremark, Inc. Mr. Gilbert stated that CVS was aware of the pill mill and/or pain clinic situation and the diversion of controlled substances, primarily oxycodone, in Florida. Mr. Gilbert further stated that CVS was seeking additional guidance from DEA to better understand the diversion issue(s) in Florida.

28. DEA and DOH advised CVS that the diversion of oxycodone, primarily originating from purported pain clinics, involves fraudulent prescriptions, doctor shoppers, and unethical doctors. CVS was further advised of the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam); (b) many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain); and (e) individuals driving long distances to visit physicians and/or to fill prescriptions.

29. CVS 219's and CVS 5195's District Supervisor, Jennifer Lalani, acknowledged that she was aware of an increase in the number of oxycodone prescriptions that have been presented to CVS pharmacies, especially in the Orlando, Florida area. Ms. Lalani also made reference to an October 2010 letter sent to pharmacies from Hillsborough County Sheriff David Gee. In that letter, Sheriff Gee made a plea to area pharmacies to work with law enforcement and closely scrutinize the prescriptions they receive in order to deal with the prescription drug epidemic in Florida. Attachment 4.
30. Ms. Lalani stated that CVS pharmacists had been instructed to verify oxycodone prescriptions by calling the prescribing practitioner. DEA informed the CVS representatives that verifying that the prescription was written by a physician was not the same as making an independent determination that the prescription was written for a legitimate medical purpose in the usual course of professional practice.
31. During the meeting, DEA provided the CVS representatives with a one-page summary of the oxycodone purchases made by CVS 219. Attachment 5. This information was contained within a summary from DEA's Automation of Reports and Consolidated Orders System (ARCOS) records that track the purchases of narcotic controlled substances between DEA registrants. The summary showed a huge increase in oxycodone purchases by CVS 219 from 2006 through 2010. Specifically, the pharmacy ordered approximately 265,000 dosage units of oxycodone in 2006. DEA informed the CVS representatives that this amount represented more than four times the amount of oxycodone a typical pharmacy orders in one year. Additionally, through October 2010, CVS 219 ordered more than 1.8 million dosage

units of oxycodone. DEA informed the CVS representatives that this 10 month order history represented more than thirty times what a typical pharmacy ordered in one year.

32. Ms. Lalani confirmed that CVS 219 was located in Sanford, Florida and was under her supervision. Ms. Lalani agreed that the volume of oxycodone purchased by this pharmacy was extremely high; however, Ms. Lalani was unable to explain why the volume was so high. Ms. Lalani further stated that she would look into the matter.
33. On August 12, 2011, DEA hosted a second meeting with CVS at the DEA Weston Resident Office. In attendance at the meeting were DEA representatives and 24 supervisors/managers from various South Florida CVS pharmacies. Attachment 6. Jennifer Lalani was again present at this meeting. Ms. Lalani stated that she wanted to attend the meeting even though she did not supervise South Florida CVS pharmacies.
34. The meeting commenced with a brief power point presentation by DEA. Attachment 7. The presentation included statistical information from DEA, Florida Department of Law Enforcement, Center for Disease Control, and the United States Census Bureau. This information showed drastic increases in prescription drug overdose deaths. It also showed that during 2010, Florida pharmacies purchased far more oxycodone than pharmacies in any other state. DEA informed the CVS representatives that the average U.S. pharmacy purchased approximately 69,500 dosage units of oxycodone in 2010, and that the average Florida pharmacy purchased approximately 134,000 dosage units of oxycodone in 2010.

35. DEA explained to the CVS representatives that, pursuant to 21 C.F.R. § 1306.04(a), a prescription for controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice, and that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but that a corresponding responsibility rests with the pharmacist who fills the prescription.
36. CVS was again advised of the typical “red flags” associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the “red flags” discussed included: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; (e) individuals driving long distances to visit physicians and/or to fill prescriptions; (f) customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and (g) customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).
37. DEA provided the CVS representatives with a list of the top 34 CVS pharmacies in Florida for purchasing oxycodone in 2010. Attachment 8. CVS 219 ranked first on this list and CVS 5195 ranked second. Ms. Lalani acknowledged that CVS 219 and CVS 5195 were under her supervision. Ms. Lalani stated that she knew CVS 219 and CVS 5195 were two of the busiest CVS pharmacies in the state, and attributed this to

the fact that the pharmacies were open 24 hours a day and were located off of Interstate-4.

DEA Investigation of CVS 219 and CVS 5195

38. DEA's investigations of CVS 219 and CVS 5195 stemmed from DEA's investigation of the pharmacies' main distributor, which was Cardinal Health, Inc.'s Lakeland, Florida branch (Cardinal). DEA's investigation of Cardinal revealed that from January 1, 2008 through October 31, 2011, Cardinal sold over 12.8 million dosage units to its top four customers. From 2008 to 2009, Cardinal's oxycodone sales to its top four retail pharmacy customers increased approximately 803%, and from 2009 to 2010, Cardinal's oxycodone sales increased approximately 162%. Attachment 9. Between 2009-2011, Cardinal's oxycodone sales to its top four retail pharmacies increased 241%. CVS 219 and CVS 5195 were two of Cardinal's top four retail pharmacy customers during this time period.
39. Compared to the average number of dosage units distributed monthly to Cardinal's other Florida retail pharmacies, the average monthly distribution at CVS 219 and CVS 5195 was staggering. Cardinal's other Florida retail pharmacies received, on average, 5,364 dosage units per month from October 1, 2008 through December 31, 2011. Attachment 10. In contrast, CVS 5195 purchased approximately 58,223 dosage units per month and CVS 219 purchased 137,994 dosage units per month during this same period. Attachment 9.
40. On October 18, 2011, based on DEA's evaluation of ARCOS data indicating that CVS 219 and CVS 5195 were purchasing high volumes of oxycodone from Cardinal,

DEA executed Administrative Inspection Warrants (“AIWs”) at CVS 219 and CVS 5195.

41. During the execution of the AIWs and thereafter, DEA personnel interviewed employees for both CVS 219 and CVS 5195. These interviews revealed the following:

- a. The Pharmacist in Charge (PIC) at CVS 219, Paras Priyadarshi, stated that the majority of the diagnosis codes listed by the prescribing practitioners on the oxycodone prescriptions were the same, and that customers requested certain brands of oxycodone, referring to them as “Ms” or “blues.”¹ PIC Priyadarshi stated that he did not see anything wrong with two individuals living at the same address receiving the same exact prescriptions for oxycodone, alprazolam and muscle relaxants from the same practitioner. PIC Priyadarshi stated that no one from CVS/Caremark, Inc. had said anything to him regarding the large amounts of oxycodone purchased by CVS 219 or the prescriptions for oxycodone being filled by CVS 219.
- b. One of the pharmacists (RPh) at CVS 219, Susan Masso, stated that many of the patients receiving oxycodone prescriptions received the same “cocktail” of prescriptions, including: oxycodone 30mg, oxycodone 15mg, alprazolam 2mg and carisoprodol. RPh Masso went on to say that she was not a “police officer and [could] not police the patients.” RPh Masso stated that some customers asked for their oxycodone prescriptions to be filled using “blues.”
- c. The Pharmacist in Charge (PIC) at CVS 5195, Jessica Merrill, stated that she set a daily limit of how many oxycodone 30mg prescriptions the pharmacy would fill each day. The limit was set based upon the amount of oxycodone the pharmacy had on-hand each day. PIC Merrill said that the reason she set this daily limit was to ensure that the pharmacy had enough oxycodone 30mg to fill the prescriptions for “real pain patients.” PIC Merrill stated that she noticed that patients brought in the same combination of controlled substance prescriptions, and that many of the oxycodone prescriptions were written for similar quantities. PIC Merrill stated that many patients paid for their oxycodone prescriptions with cash or a discount card. She also recalled instances where a vehicle would pull up to the pharmacy’s drive through window with multiple people in the car, and two or more individuals in the vehicle would present prescriptions for the same controlled substances at the same quantities, on prescriptions written by the same practitioner. PIC Merrill admitted that these

¹ “Ms” or “blues” are street slang terms used to describe Mallinckrodt brand oxycodone tablets.

prescriptions probably were not legitimate and further described the pharmacy's oxycodone customers as "shady."

- d. The Store Manager at CVS 5195, Shawn Porter, stated that one of his job duties was to act as the "bouncer" for the store. Mr. Porter elaborated on this point by stating that sometimes he had to escort customers off the premises because the customers became belligerent after the pharmacy refused to fill their prescriptions for controlled substances. Mr. Porter described these particular customers as being "hooked."
- e. The Lead Pharmacy Technician (PT) at CVS 5195, Mari Morrell, stated that CVS 5195 had experienced an increase in its sales of oxycodone. PT Morrell also stated that CVS 5195's customers knew about the store's policy to only fill a certain number of oxycodone prescriptions per day, and that the prescriptions for oxycodone were filled on a "first come first served" basis. PT Morrell said that customers would arrive at the pharmacy very early each day in order to ensure their prescriptions for oxycodone could be filled. PT Morrell went on to say that the daily limit for oxycodone 30mg prescriptions was usually reached sometime between 10:00 a.m. and 12:00 p.m. each day, but that sometimes the daily limit was reached within thirty minutes of the pharmacy opening. PT Morrell also stated that it was not her job to "police the patients."
- f. One of the pharmacists (RPh) at CVS 5195, Mark Mascitelli, stated that CVS 5195 "could fill oxycodone prescriptions all day." He stated that due to the limited number of oxycodone prescriptions the pharmacy would fill each day, customers would start lining up outside the store at around 7:45 a.m. RPh Mascitelli sometimes had to ask these customers to disperse and return when the pharmacy opened at 8:00 a.m. RPh Mascitelli said that the daily limit for oxycodone prescriptions was usually reached within one half-hour to a couple of hours of the pharmacy opening each day. RPh Mascitelli went on to say that some customers asked for their oxycodone prescriptions to be filled using "Ms" or "Vs."²

42. CVS 219 and CVS 5195 continue to employ PIC Priyadarshi and PIC Merrill.

43. During the execution of the AIW and thereafter, DEA investigators reviewed CVS 219's and CVS 5195's controlled substances prescription records and found that, since at least 2010, both pharmacies filled prescriptions for controlled substances based on prescriptions issued by practitioners who have been the subject of action by DEA or the State of Florida. DEA and the State of Florida have taken criminal, civil

² "Vs" is the street slang terms used to describe the Qualitest brand oxycodone tablets.

or administrative action against at least twenty physicians, whose customers fill their controlled substance prescriptions at CVS 219 and CVS 5195, for activities resulting in the diversion of controlled substances, including for inappropriately prescribing excessive and inappropriate quantities of controlled substances and issuing prescriptions not for a legitimate medical purpose or outside the usual course of professional practice. These actions resulted in the loss of authority of these practitioners to handle controlled substances. Many of these practitioners subsequently voluntarily surrendered their DEA registrations for cause, based on their failure to comply with the Controlled Substances Act and DEA regulations.

The practitioners include the following:

- a. Carlos A. Almonte, M.D.: DEA Immediate Suspension Order dated February 18, 2011; voluntarily surrendered registration for cause on February 23, 2011;
- b. Stephen Anthony, M.D.: voluntarily surrendered registration for cause on March 24, 2011;
- c. Mladen Antolic, M.D.: DEA Order to Show Cause dated August 8, 2011; Final Order dated January 25, 2012;
- d. Anthony Attala, M.D.: voluntarily surrendered registration for cause on March 21, 2011;
- e. Lynn E. Averill, M.D.: DEA Immediate Suspension Order dated March 9, 2011; registration retired on August 1, 2011;
- f. Scott Becker, M.D.: DEA Immediate Suspension Orders dated February 18, 2011 and March 4, 2011; voluntarily surrendered registrations for cause on May 13, 2011;
- g. Bernard Cantor, M.D.: voluntarily surrendered registrations for cause on May 10, 2011;
- h. John Christensen, M.D.: voluntarily surrendered registration for cause on September 4, 2011;

- i. Jack A. Danton, M.D.: DEA Immediate Suspension Order dated November 19, 2010; Final Order dated September 30, 2011;
- j. Manuel J. Fernandez, M.D.: DEA Immediate Suspension Order dated December 14, 2010; voluntarily surrendered registration for cause December 15, 2010;
- k. David Glickman, M.D.: Florida Order of Emergency Restriction of License dated August 19, 2010; Final Order dated March 14, 2011;
- l. Paul D. Glusman, M.D.: voluntarily surrendered registration for cause on February 7, 2011;
- m. Carlos Gonzalez, M.D.: DEA Immediate Suspension Order dated February 18, 2011; voluntarily surrendered registration for cause on September 30, 2011; Final Order dated October 11, 2011;
- n. Riyaz A. Jummani, M.D.: Florida Order of Emergency Restriction of License dated June 2, 2011;
- o. John T. Legowik, M.D.: DEA Immediate Suspension Order dated November 4, 2011; voluntarily surrendered registration for cause on November 4, 2011;
- p. Ronald Lynch, M.D.: DEA Order to Show Cause dated April 4, 2008; Final Order dated January 1, 2011;
- q. Charles Neuringer, M.D.: DEA Immediate Suspension Order dated December 15, 2010; voluntarily surrendered registration for cause on December 17, 2010;
- r. Angelo V. Pace, M.D.: DEA Immediate Suspension Order dated February 15, 2011; voluntarily surrendered registration for cause on February 23, 2011;
- s. Ataur Rahman, M.D.: voluntarily surrendered registration for cause on September 28, 2010;
- t. Nader H. Shehata, M.D.: DEA Immediate Suspension Order dated March 4, 2011; voluntarily surrendered registration for cause on April 27, 2011; and
- u. Randall L. Wolff, M.D.: DEA Immediate Suspension Order dated December 14, 2010; Final Order dated February 1, 2012.

None of these practitioners were located in Sanford, Florida, where CVS 219 and CVS 5195 were located. In fact, all but four of the above listed practitioners were located in South Florida, which is generally about 200 miles from Sanford, Florida. Accordingly, customers filling the prescriptions for controlled substances issued by these South Florida practitioners at CVS 219 and CVS 5195 had to travel lengthy distances in order to obtain their controlled substances. The investigation of these practitioners and the results of those investigations illustrated the fact that CVS did not have adequate measures in place—or at least none that were actually practiced by the employees at CVS 219 and 5195—to fulfill their corresponding responsibility to ensure that these prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

44. DEA's investigations of CVS 219 and CVS 5195 also included a review and analysis of ARCOS records showing CVS 219's and CVS 5195's purchases of controlled substances. This review and analysis revealed that:

- a. From January 1, 2008 through December 31, 2011, CVS 219 purchased over 5.8 million dosage units of oxycodone products from its distributors, primarily from Cardinal. Attachment 11.
- b. From January 1, 2008 through December 31, 2011, CVS 5195 purchased over 2.2 million dosage units of oxycodone products from Cardinal. Attachment 12.
- c. From January 1, 2010 through December 31, 2011, CVS 219 purchased, on average, approximately 160,000 dosage units of oxycodone per month. During this same time period, CVS 5195 purchased, on average, approximately 87,000 dosage units of oxycodone per month. Attachments 13 and 14.
- d. From 2008 to 2009, CVS 219 increased the amount of oxycodone it purchased by approximately 75%, from 719,400 dosage units of oxycodone in 2008 to 1.25 million dosage units of oxycodone in 2009. Attachments 11 and 15. During this same time period, CVS 5195

increased the amount of oxycodone it purchased by 56%, from 66,900 dosage units of oxycodone in 2008 to 104,500 dosage units of oxycodone in 2009. Attachments 12 and 15.

- e. In 2010, CVS 219 purchased over 2 million dosage units of oxycodone, an approximately 63% increase over 2009. Attachments 11 and 15. In 2010, CVS 5195 purchased 885,900 dosage units of oxycodone, a 748% increase over 2009. Attachments 12 and 15. In comparison, the average Florida pharmacy purchased approximately 135,000 dosage units of oxycodone during the entirety of 2010. Attachment 16.
 - f. In 2011, CVS 219 purchased over 1.8 million dosage units of oxycodone and CVS 5195 purchased over 1.2 million dosage units of oxycodone. Attachments 11 and 12. In comparison, the average Florida pharmacy purchased approximately 111,000 dosage units of oxycodone during the entirety of 2011. Attachment 25.
 - g. Between October 2011 and December 2011, CVS 219's purchases of oxycodone decreased by 77% (from 159,000 dosage units to 37,300 dosage units). During this same time period, CVS 5195's purchases of oxycodone decreased by 84% (from 63,000 dosage units to 9,900 dosage units). Attachment 14. Despite the reduction, however, CVS 219's and CVS 5195's monthly purchases of oxycodone remained higher than that of the average Florida pharmacy, which was 7,831 dosage units between October 2011 and December 2011. Attachment 14.
45. On October 19, 2011, DEA requested from CVS 219 and CVS 5195 the controlled substance dispensing profiles for twenty-two practitioners. Attachment 17.³
- Approximately one month later, CVS/Caremark, Inc. informed DEA that it was suspending the dispensing of any Schedule II narcotic prescriptions issued by these same twenty-two practitioners for a period of sixty days.⁴ Attachment 18.⁵
46. On October 20, 2011, CVS/Caremark, Inc. provided DEA with a copy of its policies regarding filling prescriptions for controlled substances. Attachment 19. These

³ Attachment 18 reflects that this request was made for twenty-four practitioners; however, two of the practitioners on the list of names provided to CVS 219 and CVS 5195 were duplicates. These names have been redacted to protect the personally identifying information of the practitioners.

⁴ The twenty-two practitioners for whom DEA was requesting the controlled substance dispensing profiles were not the same practitioners listed in paragraph 43, *supra*.

⁵ The names of the individual practitioners have been redacted.

“Dispensing Guidelines for Pain Management” provided a list of warning signs to assist CVS employees in identifying “inappropriate prescription-seeking behavior.”

47. On December 23, 2011, CVS/Caremark, Inc. provided DEA with another copy of its policies regarding filling prescriptions for controlled substances, as well as excerpts from various trainings, guides, and memoranda regarding filling prescriptions for controlled substances. Attachment 20.
48. On January 27, 2012, CVS/Caremark, Inc. provided DEA with a copy of its revised dispensing guidelines for prescriptions for controlled substances. Attachment 21.
49. A comparison of CVS/Caremark, Inc.’s revised dispensing guidelines with their previous guidelines and trainings revealed that the revised guidelines were largely the same as CVS/Caremark, Inc.’s previous policies. Further, given that employees at CVS 219 and CVS 5195 failed to follow CVS/Caremark, Inc.’s previous policies, the implementation of the revised dispensing guidelines was granted little weight.

Results of CVS 219 and CVS 5195 Investigations

Staggeringly High-Volume Purchases:

50. CVS 219 and CVS 5195 are located in Sanford, Florida. During 2011, CVS 219 purchased over 1.8 million dosage units of oxycodone and CVS 5195 purchased over 1.2 million dosage units of oxycodone. According to the 2010 U.S. Census Bureau Facts Sheet, Sanford, Florida has a population of 53,570. Attachment 22.
- Based on these numbers, CVS 219’s and CVS 5195’s dispensing of oxycodone could supply every resident of Sanford, Florida with approximately 56 dosage units of oxycodone.

51. In 2011, CVS 219 purchased 1,802,100 dosage units of oxycodone and CVS 5195 purchased 1,210,400 dosage units of oxycodone. This volume dwarfs the oxycodone volume purchased by other chain pharmacies in the Sanford, Florida area. In close proximity to CVS 219 stand two pharmacies – Walgreens #6970, located at 3803 S. Orlando Drive, Sanford, Florida, and Wal-Mart Pharmacy #10-0857, located at 3653 Orlando drive, Sanford, Florida. Walgreens #6970 purchased 176,500 dosage units of oxycodone in 2011. Wal-Mart Pharmacy #10-0857 purchased 30,500 dosage units of oxycodone in 2011. Walgreens and Wal-Mart are each located within one (1) mile of CVS 219. Attachment 23. Additionally, in close proximity to CVS 5195 stands a Publix Pharmacy #0641, located at 5240 West State Road 46, Sanford, Florida 32771. The Publix Pharmacy, as compared to CVS 5195, only purchased 25,700 units of oxycodone in 2011. The two pharmacies are located within two (2) miles of one another. Attachment 24.

52. Although CVS 219's and CVS 5195's purchases of oxycodone decreased between October 2011 and December 2011, *see* Attachments 13 and 14, their monthly purchases of oxycodone remained higher than that of the average Florida pharmacy. Attachment 14.

Failure to Fulfill Their Corresponding Responsibility:

53. From at least 2008 to 2011, CVS 219 and CVS 5195 dispensed controlled substances based upon illegal prescriptions issued by practitioners working at pill mills. DEA and the State of Florida have taken criminal, civil or administrative action against at least twenty practitioners, listed above, whose customers fill their controlled substance prescriptions at CVS 219 and CVS 5195.

54. Employees at both CVS 219 and CVS 5195 filled prescriptions for controlled substances even when they knew or should have known that a large number of the prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. These employees ignored many typical red flags of controlled substance diversion, such as: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; and (e) customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician. The employees who consistently ignored the red flags of controlled substance diversion are still working at CVS 219 and CVS 5195, despite the fact that these individuals continued to fill prescriptions for controlled substances when they knew, or should have known, that a large number of these prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.
55. CVS's November 2011 decision that it would no longer fill Schedule II narcotic prescriptions for twenty-two Florida practitioners, *see supra* ¶ 45, was not a proactive measure taken by CVS/Caremark, Inc. after making an independent determination that the twenty-two practitioners at issue may be issuing invalid prescriptions. Rather, it was simply a reaction to heightened scrutiny by DEA, and one made only after DEA requested dispensing information on these very same practitioners.

Failure to Follow CVS/Caremark, Inc. Policies:

56. The implementation of CVS/Caremark, Inc.'s revised controlled substance dispensing guidelines in January 2012 did not ensure that CVS 219 and CVS 5195 would not continue to dispense controlled substances based on prescriptions that were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. As an initial matter, many of the guidelines listed in the revised guidelines of January 2012 were simply a reiteration of the guidelines listed in CVS/Caremark, Inc.'s previous policies and trainings. Moreover, the AIW interviews conducted with employees at CVS 219 and CVS 5195 showed that the pharmacies were dispensing controlled substances even with the existence of the "warning signs" listed in the company's previous controlled substance dispensing guidelines and trainings. Because CVS 219 and CVS 5195 failed to follow CVS Caremark, Inc.'s previous controlled substance dispensing guidelines in any meaningful way, DEA had no reason to believe that the implementation of revised controlled substance dispensing guidelines would do anything to change the practices employed at CVS 219 and CVS 5195.

DEA Issues Immediate Suspension Orders for CVS 219 and CVS 5195

57. Through my training and experience as both a law enforcement officer and as a licensed pharmacist, I believe that the CVS 219's and CVS 5195's DEA registration to handle and distribute any type of controlled substance poses an imminent danger to the public health and safety. I participated in the decision-making process leading up to the issuance of the ISOs. The information in all the foregoing paragraphs informed

my decision to recommend to the Administrator that ISOs were the appropriate course of action against CVS 219 and CVS 5195.

58. DEA has scheduled an administrative hearing in the CVS 219 matter for April 3, 2012 and in the CVS 5195 matter for April 10, 2012. Absent any request for delay by CVS 219 or CVS 5195 and assuming that the Court does not enjoin the ISOs, DEA expects to conclude agency proceedings by August.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on:

2/24/12


JOSEPH T. RANNAZZISI

EXHIBIT D

Feb. 15. 2012 10:44AM

ZUCKERMAN SPADER

No. 5686 P. 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HOLIDAY CVS, L.L.C.
d/b/a CVS/Pharmacy #5195/219

Plaintiff,

vs.

ERIC H. HOLDER, JR., et al.,

Defendants.

CIVIL ACTION FILE NO.: 12-CV-191

DECLARATION OF PARAS PRIYADARSHI
PURSUANT TO 28 U.S.C. § 1746

1. My name is Paras Priyadarshi. I am the Pharmacist in Charge ("PIC") at CVS Store No. 219 in Sanford, Florida ("Store 219"). I have personal knowledge of the facts stated herein. If asked to do so, I could testify truthfully about the matters in this Declaration.

2. I make this Declaration in support of the application by CVS Pharmacy, Inc. for a preliminary injunction prohibiting the immediate suspension of Store 219's registration to dispense controlled substances.

3. I received my Pharmacy Degree from the College of Pharmacy at St. John's University, New York, in 1995.

4. I accepted a pharmacist position at Eckerd in 1996, and have been a pharmacist for Eckerd/CVS since that time. I have been the PIC at Store 219 for five years.

5. I am a licensed pharmacist in the state of Florida. With the sole exception of a disciplinary proceeding for failure to submit adequate continuing education hours for the time period of 2001 through 2003 (copy attached hereto as Exhibit A), no disciplinary actions have been taken against me during my career.

6. I have reviewed the February 2, 2012 Order to Show Cause and Immediate

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ZUCKERMAN SPADER

No. 5686 P. 4

Suspension of Registration for Store 219, and particularly paragraph 4(b), which purports to attribute a certain statement to me. Paragraph 4(b) does not accurately characterize statements I have made in the past during my cooperation with DEA investigators.

7. I have voluntarily spoken with DEA investigators twice. I have never stated nor "admitted" that Store 219 knowingly dispensed controlled substances where the pharmacy knew or should have known that the prescriptions were not issued for a legitimate medical purpose or in the usual course of professional practice.

I declare under penalty of perjury that the foregoing is true and correct. Executed
February 15, 2012.


PARAS PRIYADARSHI

EXHIBIT E

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

HOLIDAY CVS. L.L.C.
d/b/a CVS/Pharmacy #5195/219

Plaintiff,

vs.

ERIC H. HOLDER, JR., et al.,

Defendants.

CIVIL ACTION FILE NO.: _____

**DECLARATION OF JESSICA MERRILL
PURSUANT TO 28 U.S.C. § 1746**

1. My name is Jessica Merrill. I am the Pharmacist in Charge ("PIC") at CVS Store No. 5195 in Sanford, Florida ("Store 5195"). I have personal knowledge of the facts stated herein. If asked to do so, I could testify truthfully about the matters contained in this Declaration.

2. I make this Declaration in support of the application by CVS Pharmacy, Inc. for a temporary restraining order prohibiting the immediate suspension of Store 5195's registration to dispense controlled substances.

Background

3. I completed my Bachelors at the University of Central Florida in 1997, and I received my Pharm D., *cum laude*, from the University of Florida in 2009.

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4. I worked for CVS as a Pharmacy Intern from 2005 through 2009, while I was in pharmacy school. After graduation, I accepted a Pharmacist position at Store 5195 and at the end of 2009, I became the PIC at Store 5195.

5. I am a licensed pharmacist in the state of Florida. No disciplinary actions have been taken against me during my career. As a licensed pharmacist, I took an oath to ensure the appropriate care of patients who seek my services, including those in severe pain who require prescribed medications, such as oxycodone.

6. I supervise the staff of pharmacists and pharmacy technicians in Store 5195.

7. I estimate that in mid-October of 2011, Store 5195 was filling between two-hundred eighty (280) and four-hundred twenty (420) total prescriptions per day, although I have not reviewed specific data regarding these numbers.

8. I have never filled a controlled substance prescription, nor directed anyone else to do so, based on a belief that filling such a prescription would affect any bonus I received from CVS.

9. I have never felt pressured to fill prescriptions for controlled substances. I always use my independent professional judgment in dispensing prescriptions. I instruct the pharmacists under my supervision to likewise use their independent professional judgment.

Communications with the DEA

10. I have reviewed the February 2, 2011 Order to Show Cause and Immediate Suspension of Registration for Store 5195, and particularly paragraph 4(b),

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which purports to attribute certain statements to me. Paragraph 4(b) does not accurately characterize statements I have made in the past during my cooperation with DEA investigators.

11. On October 18, 2011, I was interviewed by Ruth Carter, a Diversion Investigator with the DEA. During that interview, I never stated or "admitted" that Store 5195 had knowingly dispensed controlled substances where the pharmacy knew or should have known that the prescriptions were not issued for a legitimate medical purpose or in the usual course of professional practice. I have always issued prescriptions in accordance with my professional obligations and never for an improper purpose.

12. Furthermore, I have never set daily limits or quotas on how many oxycodone prescriptions Store 5195 fills each day in order to reserve oxycodone for "real pain patients." Indeed, I don't recall ever using the term "real pain patients" in my discussions with the DEA.

13. While I am not trained to diagnose patients, I take my responsibilities regarding the proper dispensing of controlled substances seriously. I am mindful of, and abide by, the law at all times while caring for my patients.

14. During my October 18, 2011 interview with Diversion Investigator Carter, I recall asking her if the DEA had any information they could share with me to assist me in exercising my professional judgment (e.g., information about certain doctors that the DEA is suspicious of). Diversion Investigator Carter replied that I should not fill oxycodone prescriptions for "shady" people. When I asked what "shady" meant, I recall

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she told me that all people filling oxycodone prescriptions, except cancer patients, are not legitimate pain patients and that they are just drug seekers.

Safeguards related to oxycodone prescriptions that have been in place since before October, 2011

15. Prior to October of 2011, I adopted various safeguards at Store 5195 in an effort to prevent the abuse or diversion of prescription drugs, including controlled substances.

16. In particular, I implemented stringent scrutiny and verification procedures for oxycodone prescriptions filled at Store 5195. These procedures require that pharmacists and pharmacy techs at Store 5195 confirm the legitimacy of a prescription for oxycodone before it is filled.

17. Under the policies at Store 5195, pharmacists and pharmacy techs are expected to check oxycodone patient information, including identification, date of birth, and CVS electronic profile. These procedures include: a) a review of any past denials of prescriptions or multiple prescribers; b) a determination of whether the patient is due for a new prescription; and c) documentation of the diagnosis code for the prescription.

18. I have also directed pharmacists and technicians at Store 5195 to confirm all oxycodone prescriptions with the prescribing provider by contacting that provider or his office. Once the provider confirms the existence of the prescription, that information is documented on the back of each oxycodone prescription.

19. Furthermore, I have instructed pharmacists and technicians to decline to fill oxycodone prescriptions for patients with pinpoint pupils, patients who are aggressive, or patients who cannot show a consistent medical history (*i.e.*, a stable, established relationship with the prescribing physician, a regular routine with respect to choice of pharmacy, and appropriate refill patterns).

20. Our policy at Store 5195 also directs pharmacists and technicians to decline to fill oxycodone prescriptions from a provider if there is any indication that the provider is being investigated by state or federal authorities for writing bad prescriptions, or if the provider is not cooperative with Store 5195's efforts to verify prescriptions. Store 5195 keeps an internal "Do Not Fill" list identifying these providers.

21. When a pharmacist or technician at Store 5195 suspects a patient is doctor shopping, he or she is expected to complete a form entitled the "Record of Multi-Doctor Narcotic Overlap." Copies of these forms have been maintained in a binder in Store 5195 (along with other information relating to denied prescriptions), and these forms have been made available to local law enforcement. I understand that this binder is now in the possession of the DEA.

22. I regularly communicate with Seminole County law enforcement regarding suspicions of controlled substance diversion, and I have assisted in at least fifteen arrests related to oxycodone since I began working at Store 5195. I have received numerous favorable comments from local law enforcement relating to my efforts in this regard.

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23. I estimate that, in the months prior to mid-October, 2011, Store 5195, pursuant to the protocols described above, declined to fill an average of thirty (30) to thirty-five (35) prescriptions per day.

24. In addition, based on the procedures described above, I estimate that Store 5195 has voided over five hundred (500) prescriptions in the past year, of which approximately three-hundred eighty (380) were controlled prescriptions.

Safeguards related to oxycodone prescriptions implemented after October, 2011

25. In October of last year, the U.S. Drug Enforcement Administration ("DEA") issued an administrative warrant of inspection for Store 5195. In addition, DEA agents interviewed me, and at all times I cooperated with this inquiry. At that time it became clear to me that DEA had concerns about the volume of oxycodone being dispensed from Store 5195, despite the existing safeguards described above.

26. In response to these concerns, additional safeguards were implemented at Store 5195 related to oxycodone prescriptions.

27. I limited the geographical area of doctors and patients, from which the pharmacy will fill oxycodone prescriptions.

28. At my own expense, I enrolled "EFORSCE," a new program initiated by the state board of pharmacy that gives healthcare professionals access to an electronic database of individual patients' controlled substance prescription histories.

29. Since mid-October 2011, pharmacists and technicians at Store 5195 were directed not to accept any new oxycodone prescriptions. This policy includes not filling

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oxycodone prescriptions for patients who were previously filling prescriptions at another CVS pharmacy, and who then sought to fill new prescriptions at Store 5195.

30. Under our current policy at Store 5195, pharmacists are directed to interview every patient presenting an oxycodone prescription. The patient is to be questioned regarding, among other topics, the type of injury or illness the patient has been diagnosed with, the patient's expected treatment plan and length of time the patient expects to be on oxycodone, and whether the patient is aware of the dangers of opiates and the importance of taking the drug only as directed. Records of these patient interviews are kept and maintained at Store 5195.

31. Under our policy, oxycodone prescriptions may not be presented at the drive-thru window. The patient must present the prescription in the store so the patient can be more fully evaluated, captured on Store 5195's security cameras, and interviewed by the pharmacist.

32. On November 21, 2011, CVS suspended dispensing Schedule II narcotics for 22 area practitioners. Historically, these 22 prescribers represented the majority of oxycodone prescriptions filled at Store 5195. Store 5195 has implemented procedures to comply with this suspension.

33. In addition, corporate dispensing guidelines have been revised and reinforced. I received the attached guidelines for dispensing narcotic drugs for pain treatment in January 2012 (Exhibit 1). I have reviewed these dispensing guidelines with the pharmacy staff, both on an individual basis and in group settings.

34. Store 5195 participated in an audit conducted by former DEA personnel currently employed by an independent third party specializing in DEA compliance.

Current dispensing at Store 5195

35. Based upon the additional safeguards and further measures taken in response to DEA's concerns, and our historical policies, Store 5195's ability to detect and prevent abuse or diversion of oxycodone and other controlled substances continues to improve significantly.

36. The number of oxycodone prescriptions dispensed by Store 5195 declined significantly since October of 2011.

37. The decline in prescriptions also resulted from the suspension of the 22 prescribers described above.

38. Currently, Store 5195 is filling an average of approximately fifteen oxycodone prescriptions per week. This equates to roughly 1,100 oxycodone tablets per week.

39. I understand that the DEA's focus is on oxycodone; however I am further advised that Store 5195 is now prohibited from dispensing any controlled substances. Oxycodone is only one of many Schedule II controlled substances. Further, there are many controlled substances identified in Schedules III through V. Patients are in need of these non-oxycodone controlled substances.

40. I believe that if Store 5195 is not permitted to dispense controlled substances, many of the pharmacy's regular customers, who obtain prescriptions for both

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controlled and non-controlled substances, would take their pharmacy business elsewhere. Some of these patients may likely become permanent customers at one of Store 5195's competitors.

41. Finally, Store 5195's inability to fill prescriptions for controlled substances will negatively impact patients who have formed a relationship with their pharmacist at Store 5195. Those patients will no longer be able to utilize a healthcare professional that they trust and who is familiar with their personal healthcare history.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 6, 2012.


JESSICA MERRILL

Merrill Declaration

Ex. 1

CVS Caremark**PROTOCOL FOR DISPENSING NARCOTIC DRUGS
FOR PAIN TREATMENT**

Pharmacists must exercise their professional judgment to meet potentially conflicting challenges posed by the therapeutic imperative to optimize outcomes and the regulatory imperative to prevent drug diversion. State and Federal laws and regulations impose a corresponding responsibility on pharmacists to dispense medicine only for legitimate medical purposes and CVS Caremark seeks to ensure that its pharmacists are fulfilling that corresponding duty at all times.

CVS Caremark expects and supports decisions by its pharmacists to *not* fill prescriptions if, in the sound exercise of their professional and clinical judgment they believe or suspect that the prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

Below are some important guidelines for pharmacists:

1. You should suspend filling *all controlled substance prescriptions* from practitioners you believe or have reason to doubt are issuing prescriptions for legitimate medical purposes in the course of a valid doctor/patient relationship. Notify your pharmacy supervisor of such action.
2. You should exercise particular caution before filling a prescription:
 - a. if you believe or have reason to doubt that the practitioner has issued the prescription for a legitimate medical purpose in the course of a legitimate doctor /patient relationship, regardless of whether the prescription is otherwise "valid" on its face;
 - b. from practitioners who prescribe the same medication in the same dosage amounts to *most or all* of their patients (e.g., oxycodone 30mg, 180 dosage units) - the use of prescriptions that are preprinted or stamped with the drug type and amount should be cause for concern;
 - c. from practitioners who *routinely* prescribe the same combination of drugs for pain treatment for *most or all of their patient, particularly where DEA has identified that combination as potentially abused* (e.g., oxycodone, alprazolam and Soma);
 - d. from practitioners who you are aware do not take insurance or whose patients have insurance but always insist on paying cash for their prescriptions;

- e. from individuals who come to the pharmacy in groups to get narcotic prescriptions filled;
- f. that appears to have been altered or forged – verify any questionable prescription information with the practitioner and adhere to the guidance set forth in the *Policy Regarding Suspected Fraudulent or Altered Prescriptions* (attached);
- g. where the patient requests the drug by description, such as, “Mallinckrodt blues,” “M’s” or “the blue pill”; and
- h. where the patient appears visibly altered, intoxicated or incoherent.

Remember that you have the authority to decline to fill any prescription where, in the exercise of your professional and clinical judgment, you believe or suspect that it was not issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.

3. CVS pharmacists should *not* refer any patient/prescription to another CVS pharmacy if the first pharmacist would not, in his or her professional judgment, otherwise fill the prescription.
4. Pharmacists should ordinarily only fill prescriptions if both the patient and practitioner reside within the geographic area served by the pharmacy - any exceptions should be extraordinary, and documented in the patient files.
5. Contact the practitioner with any concerns about the type and quantity of medication prescribed for a given indication (e.g., oxycodone 30 mg prescriptions for more than 180 dosage units).
6. Contact the practitioner and verify treatment if the prescription appears to be duplicative therapy, refill too soon, or if the patient has had a prescription issued by several practitioners.
7. When dispensing a pain medication, such as oxycodone or hydrocodone, where you have no relationship with the patient and/or the prescriber, you should verify with the practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined. Document the information on the back of the prescription. Note that this verification process is but one step that a pharmacist should take to ensure that a prescription is issued for a legitimate medical purpose. Practitioner verification alone does not render a prescription legitimate.
8. Pharmacists must familiarize themselves with the DEA’s “Guidelines for Prescription Fraud,” at Appendix D of the DEA Pharmacist’s Manual (attached).

Drug Enforcement Administration
Pharmacist's Manual

APPENDIX D

Pharmacist's Guide to Prescription Fraud

The purpose of this guide is to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing diversion into the illicit market. It is not the intent of this publication to discourage or prohibit the use of controlled substances where medically indicated. However, nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under federal or state laws.

Pharmacist's Responsibilities

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As a healthcare professional, pharmacists share responsibility for preventing prescription drug abuse and diversion.

- Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion.
- The dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

Types of Fraudulent Prescriptions

Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing. Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the practitioner's prescription. They may have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Drug seeking individuals may also call in their own prescriptions and give their own telephone number as a call-back for confirmation. Drug abusers sometimes steal legitimate prescription pads from practitioner's offices and/or hospitals and prescriptions are written using fictitious patient names and addresses.

In addition, individuals may go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions. The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or improper prescribing, especially if a patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of a patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

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- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community, show up with prescriptions from the same physician.

The following criteria may indicate a forged prescription:

- Prescription looks "too good". The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting.

Prevention Techniques

- Know the prescriber and his/her signature.
- Know the prescriber's DEA registration number.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

When there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.

If at any time a pharmacist is in doubt, he /she should require proper identification. Although this procedure is not foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk. If a pharmacist believes the prescription is forged or altered, he/she should not dispense it and call the local police. If a pharmacist believes he/she has discovered a pattern of prescription abuse, he/she should contact the state Board of Pharmacy or the local DEA Diversion Field Office (Appendix K). Both DEA and state authorities consider retail-level diversion a priority issue.

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Proper Controls

Dispensing procedures without control and professional caution are an invitation to the drug abuser. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion.

Most drug abusers seek out areas where communication and cooperation between health care professionals are minimal because it makes the drug abuser's work easier. Thus, a pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie. In addition, the pharmacist should become familiar with those controlled substances that are popular for abuse and resale on the streets in the area and should discuss those findings with other pharmacists and practitioners in the community.

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